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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,221	03/23/2004	Janakraj Karamchand Mehra	124907-00111	3311

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EXAMINER	
KATAKAM, SUDHAKAR	

ART UNIT	PAPER NUMBER
1621	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/807,221	MEHRA ET AL.	
	Examiner	Art Unit	
	Sudhakar Katakam	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *8-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the application

1. Receipt of Applicant's Remarks and Arguments filed on 24th Sep 2008 is acknowledged. However, the arguments for the previous rejection for the claims are not found persuasive and as such, the following rejection has been maintained.

2. The claims 1-14 are remain pending.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Baro et al** (US 5,082,969) in view **Palmer et al** (US 6,252,113) and applicant's acknowledged prior art (Polish Patent PL 158, 497) in the specification page 2, paragraph 2.

The instant claims are drawn to a process of making 1-[4-(2-methoxyethyl) - phenoxy]- 3-[(1 - methylethyl)amino]- 2- propanol by a series of steps. See claim 1.

Baro et al teach a process of making 1-[4-(2-methoxyethyl) -phenoxy]- 3-[(1 - methylethyl)amino]- 2- propanol by a very similar method. See columns 1-2.

Baro et al fail to explicitly teach a) the reaction step "B" at a temperature of 40-45 degrees and b) the extracting of the organic phase at a pH of 7.0-8.0 using water. **Baro et al** disclosed reaction step "B" at a temperature range of 0-30 degrees.

Applicant's acknowledged prior art (Polish Patent PL 158, 497) in the specification page 2, paragraph 2, teaches a process wherein 4-(2-methoxyethyl)phenol and epichlorohydrin are reacted at 20°-80°C temperature for 3 hours under aqueous alkaline conditions. The epoxide so formed is reacted with large excess of isopropyl amine (medium as well as reactant) to yield metoprolol base.

Palmer et al which is also directed to a process of making 1-[4-(2-methoxyethyl)-phenoxy]- 3-[(1 - methylethyl)amino]- 2- propanol teaches a temperature range of step "B" of 50-70 degrees.

Thus the art as a whole reasonably suggests that the process of **Baro et al** would work at a temperature range of 20°-80°C. Thus it would have been obvious to one having ordinary skill in the art at the time that applicant's invention was made to have conducted the process of **Baro et al** at a temperature between 40-45 degrees with a reasonable expectation of success. One skilled in the art would have been motivated to modify the temperature in order to optimize the process.

The instant claimed limitation of extracting the organic phase at a pH range of 7-8 is also deemed to be unpatentable. Please note that **Baro et al** discloses the

extraction step. See for example column 1 lines 55-68 and column 2 lines 1-15. **Baro et al** is silent of the pH range of this extraction step. **Baro et al** states "after the appropriate extractions and washing...". **Baro et al** is silent of the solvent used of the pH range. However, it is reasonable to assume that water being a well known extraction solvent would produce an extraction step at a pH of 7-8. **Palmer et al** clearly shows that desire to use water as a solvent. Thus it would have been obvious at the time that applicant's invention was made to have conducted the extraction of the organic phase at a pH of 7-8. This limitation if not inherent in the process of **Palmer et al** is well within the skill of an ordinary artisan.

The instant claims directed to making salts are also obvious since the prior art taught the same salts being made. See for example claim 11 of **Palmer et al** and example 3 of **Baro et al**.

The examiner has carefully considered the 132 declaration alleging unexpected results and found it be unpersuasive. The alleged advantages of the instant invention are not reflected in the claims. For example, applicants allege that the instant invention avoids the using of an excess amount of isopropyl amine. This may or may not be true, however the claimed invention reads on use of excess amount of isopropyl amine. Applicant's claim of conducting a side-by-side comparison was found lacking.

A true side by side comparison must show that all variables are the same, including molar ratio of reactants, except for the one variable that applicants allege is responsible for unexpected results. There is no evidence of record which clearly

demonstrates that applicant's claimed invention has an unexpected advantage over the prior art of record.

Response to Arguments

6. Applicant's arguments filed on 24th Sep 2008 have been fully considered but they are not persuasive.

The examiner acknowledges applicants' argument that **Baro et al** and **Palmer et al** taken alone or in combination fail to disclose every element of the claimed invention. In particular, the reference fail to disclose the reaction temperature of 40-45^{o}C and extracting and washing the organic phase reaction product of step B at pH of 7.0-8.0.

The examiner contends, however, that the newly cited polish patent fills the gap of applicants' temperature range. With regard to pH, it is reasonable to assume that water being a well known extraction solvent would produce an extraction step at a pH of 7-8. **Palmer et al** clearly shows that desire to use water as a solvent. Thus it would have been obvious at the time that applicant's invention was made to have conducted the extraction of the organic phase at a pH of 7-8. This limitation if not inherent in the process of **Palmer et al** is well within the skill of an ordinary artisan.

The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine, 837 F.2d 1071,5 USPQ2d 1596 (Fed. Cir. 1988)and In re Jones, 958

F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it is permissible for the examiner to rely on disclosures, which fairly teach embodiments of applicant's invention. The claims require a multitude of elements and it is reasonable for one of ordinary skill in the art to consider these elements being used together.

The claims would have been obvious because, a person of ordinary skill has a good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product, not of innovation, but of ordinary skill and common sense.

The claim would have been obvious because the design incentives or market forces provided a reason to make an adaptation, and the invention resulted from application of the prior knowledge in a predictable manner.

All the claimed elements were known in the prior art and one skilled person in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to have yielded predictable results to one of ordinary skill in the art at the time of the invention.

The Supreme Court in KSR noted that if the actual application of the technique would have been beyond the skill of one of ordinary skill in the art, then the resulting invention would have been obvious because one of ordinary skill could not have been expected to achieve it.

Thus it would have been obvious to one having ordinary skill in the art at the time that applicant's invention was made to have combined the teachings of above cited prior art and to arrive at instant applicants process with a reasonable expectation of success.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhakar Katakam whose telephone number is 571-272-9929. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sudhakar Katakam/
Examiner, Art Unit 1621

/Peter G O'Sullivan/

Primary Examiner, Art Unit 1621